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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/247,886	02/10/1999	JUHA PUNNONEN	18097-030200	8163

30560 7590 09/05/2002

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EXAMINER
CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 09/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/247,886	Applicant(s) PUNNONEN ET AL.	
	Examiner Shin-Lin Chen	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-13,17-23 and 51-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-13,17-23 and 51-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10,22* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants' amendment filed 7-31 -2 has been entered. Upon further consideration of the amendment filed 7-31-02, the finality of the preceding Official action filed 4-5-02 (Paper No. 21) has been withdrawn. Claims 1, 14-16 and 65-67 have been canceled. Claims 2-13, 17-23 and 51-64 are pending and under consideration.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 2-13 and 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 38-49 of copending Application No. 09/021,769. Although the conflicting claims are not identical, they are not patentably distinct from each other because, although drawn to different scope, they encompass the same invention and obvious variants thereof.

Claims 2-13 and 17 of the present application are drawn to a method for producing and screening a recombinant cell-specific binding moiety for an ability to increase uptake or specificity of a genetic vaccine for a target cell by creating a library of vectors from a library of recombinant binding moiety encoding nucleic acid that encodes nucleic acid binding domain and a cell specific ligand, wherein the vector comprises said recombinant binding moiety and a binding site for said DNA binding domain, and a composition comprising said recombinant binding moiety and a polynucleotide sequence expressing an antigen and comprising a binding site.

Claims 38-49 of Application No. 09/021,769 are drawn to a method of obtaining an optimized recombinant cell-specific binding moiety useful for increasing uptake or specificity of a genetic vaccine vector by creating a library of vectors from a library of recombinant binding moiety encoding nucleic acid that encodes nucleic acid binding domain and a cell specific ligand,

wherein the vector comprises said recombinant binding moiety and a binding site for said DNA binding domain, and a genetic vaccine vector which comprises a cell-specific recombinant binding moiety.

Although the subject matters of claims 2-13 and 17 of the present application and claims 38-49 of Application No. 09/021,769 are not identical but they encompass the same invention and are obvious for one of ordinary skill in the art. Thus, claims 2-13 and 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 38-49 of copending Application No. 09/021,769.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 18-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 51-54 of copending Application No. 09/021,769. Although the conflicting claims are not identical, they are not patentably distinct from each other because, although drawn to different scope, they encompass the same invention and obvious variants thereof.

Claims 18-21 of the present application are drawn to a method for producing and screening a recombinant cell-specific binding moiety for an ability to increase uptake or specificity of a genetic vaccine for a target cell by creating a library of vectors from a library of recombinant nucleic acid encoding a binding moiety of an enterotoxin, recovering the

recombinant cell-specific binding moiety polypeptide from host cells and contacting said polypeptide with a cell surface receptor of a target cell, and determining enhanced ability of said polypeptide to bind to the target cell.

Claims 51-54 of Application No. 09/021,769 are drawn to a method of obtaining an optimized recombinant cell-specific binding moiety useful for increasing uptake or specificity of a genetic vaccine vector by creating a library of vectors from a library of recombinant nucleic acid encoding a non-toxic receptor binding moiety of an enterotoxin, recovering the recombinant cell-specific binding moiety polypeptide from host cells and contacting said polypeptide with a cell surface receptor of a target cell, and determining enhanced ability.

The subject matter of claims 51-54 of Application No. 09/021,769 is encompassed by that of claims 18-21 of the present application and they are obvious for one of ordinary skill in the art. Thus, claims 18-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 51-54 of copending Application No. 09/021,769.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 18-23, 51-58 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See M.E.P.. § 2172.01. The omitted steps are: how to determine whether the recombinant cell-specific binding moiety polypeptide has enhanced ability to bind to the target cell, what is the control that is compared to determine enhanced ability to bind the target cell.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 51-58 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stemmer et al. 1997 (WO 97/20078, IDS-AG) in view of Ledley et al., 1994 (WO 94/25608, IDS-AH) and Patten et al., 1997 (Current Opinion in Biotechnology, 8: 724-733, IDS-BG).

Claims 51-58 and 64 are directed to a method for producing and screening a recombinant cell-specific binding moiety for an ability to increase uptake or specificity of a genetic vaccine for a target cell by creating a library of vectors from a library of recombinant nucleic acid encoding a cell-specific binding moiety, recovering the recombinant cell-specific binding moiety polypeptide from host cells and contacting said polypeptide with a cell surface receptor of a target cell, determining enhanced ability of said polypeptide to bind to the target cell, and fusing or linking the recombinant cell-specific binding moiety polypeptide to a vaccine antigen or coating the vaccine antigen with said polypeptide, and a composition containing said cell-specific recombinant binding moiety polypeptide and the antigen. Claim 54 specifies the target cells are muscle cells, monocytes, B cells, and T cells etc. Claim 56 specifies the cell-specific binding moiety comprises a polypeptide of CD2, CD28, CTLA-4, CD40, ligand thereof, ICAM-1, Fc portion of Ig G etc.

Stemmer teaches a method for the production of nucleic acid fragments or polynucleotides encoding mutant proteins by repeated cycles of mutagenesis, shuffling and selection of nucleic acids to generate polynucleotides having desired characteristic by iterative selection and recombination for the molecular evolution *in vitro* or *in vivo* of proteins (e.g. abstract). Stemmer teaches a method of evolving a polynucleotide sequence toward a desired

property comprising recombining at least a first and second forms of the polynucleotide sequence to produce a library of recombinant forms of the sequence, screening at least a first recombinant sequence from said library, recombining said first recombinant sequence with a further form of the polynucleotide sequence, the same or different from the first and second forms, to produce a further library, and screening at least one further recombinant polynucleotide from said further library (e.g. p.164).

Stemmer does not teach generating a library of recombinant nucleic acid encoding cell-specific binding moiety polypeptide which binds to the surface of a target cell and specify target cells and cell-specific binding moiety.

Ledley teaches generating a chimeric recombinant DNA-binding protein comprising a first element for binding to a receptor on a target cell and a second element required for binding to DNA, such as histone or transacting regulatory element, and a complex for efficient gene transfer comprising a DNA molecule specifically and non-specifically bound to the chimeric recombinant DNA-binding protein (e.g. p. 26, 27, abstract). Ledley also teaches the ligands for specific or nonspecific receptors on the cell surface can be immunoglobulins, T-cell receptors, cell surface markers from lymphocytes, cell adhesion molecules, and viral proteins etc., (e.g. p. 15).

Patten teaches "viral vaccine vectors can be enhanced by DNA shuffling to give desired properties of tropism, stability and expression level", and DNA shuffling could be a tool " for

increasing the efficiency and success rate of the development of novel whole organism, viral, bacterial and recombinant protein vaccines" (e.g. p. 732).

It would have been obvious for one of ordinary skill in the art at the time of the invention to substitute the first and second forms of polynucleotide sequences taught by Stemmer with polynucleotide sequences encoding a DNA-binding element and a ligand binding to a receptor on a target cell as taught by Ledley for the production of a genetic vaccine as taught by Patten.

One having ordinary skill at the time of the invention would have been motivated to do so because the generation of a chimeric recombinant DNA-binding protein comprising a first element for binding to a receptor on a target cell and a second element required for binding to DNA could facilitate the efficiency of gene transfer and the effects of a genetic vaccine to stimulate immune response in a host.

Information Disclosure Statement

8. The information disclosure statement filed 3-29-02 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because Items 1-81 of the submitted IDS have not been provided. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with

the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 C(1).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Scott Priebe can be reached on (703) 308-7310. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Patsy Zimmerman, whose telephone number is (703) 305-2758.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.